K121501

510(k) SUMMARY

NOV 29 2012

SUMMARY OF SAFETY AND EFFECTIVENESS FOR
ARROW PRESSURE INJECTABLE JUGULAR AXILLO-SUBCLAVIAN CENTRAL CATHETER WITH CHLORAG+ARD ANTIMICROBIAL AND ANTITHROMBOGENIC TECHNOLOGY

1. Submitter Information

Name:	Arrow International, Inc. (subsidiary of Teleflex Inc.)
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Date Prepared: November 29, 2012

2. Device Name

Device Trade Name:	Arrow® Pressure Injectable Jugular Axillo-subclavian Central Catheter™ (JACC™) with Chlorag+ard® Antimicrobial and Antithrombogenic Technology
Common Name:	Central Venous Catheter
Classification Name:	Percutaneous, implanted, long-term intravascular catheter

3. Predicate Devices

Predicate 1:	ArrowEvolution™ Pressure Injectable PICC with Chlorag+ard Antimicrobial and Antithrombogenic Technology (K112896)
Predicate 2:	Arrow Pressure Injectable CVC (K071538)

4. Device Description

The Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter with Chlorag+ard Antimicrobial and Antithrombogenic Technology is a single use catheter designed to provide short-term or long-term access to the central venous system. It consists of a non-tapered, radiopaque polyurethane extruded catheter body with a softer, contoured Blue Flex Tip. The catheter is available in 4.5 Fr. Single lumen and 5.5 Fr. Double lumen configurations with usable lengths of 20, 25, and 30 cm. The catheters can be used for the injection of contrast media. The maximum recommended infusion rate is 5 mL/sec. The external catheter body and the entire internal fluid path of the device are treated with Chlorhexidine based solution technology. Studies have shown the technology to possess both antimicrobial and antithrombogenic properties.

The catheters will be packaged sterile in kits that will include components to facilitate insertion.

5. Indications for Use

The Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter (JACC) with Chlorag^{+}ard® Antimicrobial and Antithrombogenic Technology is indicated for short-term or long-term access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the Arrow Pressure Injectable JACC may not exceed 300 psi. The maximum pressure injection flow rate for the specific lumen being used for pressure injection is printed on the extension line hub.

Chlorag^{+}ard Technology treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization on catheter surfaces. Antimicrobial effectiveness was evaluated using *in vitro* and *in vivo* test methods and no correlation between these testing methods and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of existing infections.

6. Technological Characteristics and Substantial Equivalence

The Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter with Chlorag^{+}ard Antimicrobial and Antithrombogenic Technology is substantially equivalent to the ArrowEVOLUTION™ Pressure Injectable PICC with Chlorag^{+}ard Antimicrobial and Antithrombogenic Technology (K112896) in terms of overall design, manufacturing process, functional performance, and materials of construction. The indications for use, for the subject catheter, are the same as the predicate device (K112896) with the exception of the word peripheral that describes the external insertion site.

The antimicrobial agent for the subject device is the same Chlorhexidine based solution used for the ArrowEVOLUTION™ Pressure Injectable PICC with Chlorag^{+}ard Antimicrobial and Antithrombogenic Technology (K112896). The process of application of the antimicrobial agent is also the same as that of the predicate device.

The Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter with Chlorag^{+}ard Antimicrobial and Antithrombogenic Technology is substantially equivalent to the Arrow Pressure Injectable CVC (K071538) in terms of the intended use which describes a central venous access insertion point that is not peripheral.

7. Nonclinical Testing

Bench testing performed on the ArrowEVOLUTION™ Pressure Injectable PICC with Chlorag^{+}ard Antimicrobial and Antithrombogenic Technology (K112896) supports the safety and efficacy of the subject device because the subject device is the same as the predicate device in shorter lengths. The following performance testing has been completed for the predicate device and applies directly to the subject device:

- air leakage
- collapse resistance
- liquid leakage
- radio detectability
- clamp closure efficacy
- flow restriction after clamping of extension line
- internal and external CHA content
- tensile testing, catheter kinking
- ink adhesion testing
- column strength
- tip stiffness
- biocompatibility
- *in vitro* antimicrobial efficacy up to 30 days using predicate device as compared to uncoated control
- *in vivo* infection study up to 30 days using predicate device as compared to uncoated control

- *in vitro* and *in vivo* antithrombogenic effectiveness testing performed to assess platelet adhesion, patency and thrombus accumulation comparing the predicate device, the uncoated predicate PICC and the Zeus devices for up to 30 days

The following additional bench testing has been performed to specifically support the subject device, as these tests are specifically related to catheter length:

- priming volume
- gravity flow rate
- pressure injection
- static burst
- mechanical hemolysis
- whip testing

8. Conclusions

The Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter with Chlorag^{+}ard Antimicrobial and Antithrombogenic Technology is the same device as the ArrowEVOLUTION Pressure Injectable PICC with Chlorag^{+}ard Antimicrobial and Antithrombogenic Technology (K112896) with the exception of usable catheter length, insertion location and extension line printed text. The results of the testing performed have demonstrated that the devices are safe, effective, and perform as intended. The subject device and both predicate devices are intended to have the final tip position in the same location regardless of the insertion site.

In conclusion, the AM/AT JACC is substantially equivalent to the AM/AT PICC (K112896) and the PI CVC (K071538).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 29, 2012

Ms. Julie Lawson
Regulatory Affairs Specialist
Arrow International, Incorporated (Subsidiary of Teleflex, Incorporated)
2400 Bernville Road
Reading, Pennsylvania 19605

Re: K121501
Trade/Device Name: Arrow® Pressure Injectable Jugular Axillo-subclavian Central Catheter™ (JACC™) with Chlorag+ard® Antimicrobial and Antithrombogenic Technology
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: November 20, 2012
Received: November 21, 2012

Dear Ms. Lawson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121501

Device Name: Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter (JACC) with Chlorag+ard Antimicrobial and Antithrombogenic Technology

Indications for Use:

The Arrow® Pressure Injectable Jugular Axillo-subclavian Central Catheter™ with Chlorag+ard® Antimicrobial and Antithrombogenic Technology is indicated for short-term or long-term access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the Arrow Pressure Injectable JACC™ may not exceed 300 psi. The maximum pressure injection flow rate for the specific lumen being used for pressure injection is printed on the extension line hub.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Richard C. Chapman
Date: 2012.11.30 10:02:14 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number:_____